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| 08/935,377 | 09/22/1997 | MAURICE ZAUDERER | 1821.0010000 | 8588 |

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06/04/2002

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| EXAMINER |
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DECLoux, AMY M

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| ART UNIT | PAPER NUMBER |
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1644

DATE MAILED: 06/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/935,377

Applicant(s)

ZAUDERER, MAURICE

Examiner

Amy M. DeCloux

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 68-120 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 68-115 and 117-120 is/are rejected.
- 7) ☒ Claim(s) 116 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3-27-01 (Paper No.23) has been entered.

Election/Restrictions

2. Applicant's election with traverse of the following species, nucleic acids from tumor cells, vaccinia vector, p7.5/ATG1/TK, Class I MHC, and fowl pox in Paper No. 32 filed 3-4-02 is acknowledged. The traversal is on the ground(s) that it is not a serious burden to examine all the species. This is not found persuasive because essentially for the reasons of record. Each of the species represent a distinct product..

The requirement is still deemed proper and is therefore made FINAL.

Drawings

3. New formal drawings are required in this application, please see attached draftsman review Form PTO 892. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the

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Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Specification

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that

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the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The abstract of the disclosure is objected to because of the word "novel" disclosed in line 1 of the abstract. Patents are presumed to be novel. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 112-113 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 112-113 are indefinite in the recitation of "v7.5/tk" and "vEL/tk", respectively because it is not clear what these terms mean.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 68-70 and 120 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolfel et al (US Patent 5,530,096 6-25-1996).

9. Wolfel et al teach a method for selecting a nucleic acid molecule encoding a target epitope of CTL comprising contacting host cells with CTLs specific for said target epitope wherein said host cells comprise a vaccinia virus library of heterologous nucleic acid molecules encoding said target epitope in host cells, wherein said host cells express a defined MHC Class I molecule and wherein said cytotoxic T cells are restricted for said MHC molecule and recovering said host cell. Wolf et al recovering those host cells which have undergone a lytic event by measuring TNF Values (see examples 4-5) as recited in claim 68. '096 teach removing the vector from positive clones that have undergone a lytic event as recited in claim 69 (see column 5, lines 47-48).W '069 further teaches isolating the vector from the host cells and transferring them to an expression vector in a host with a defined MHC Class I molecules , contacting said cells with CTLs specific for the target epitope and restricted by said MHC molecule and recovering those cells which have undergone a lytic event as recited in claim 70 and claim 120(see Example 6).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 68-111, 114-115 and 117-120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolfel et al (US Patent 5,530,096 6-25-1996) in view of Paoletti et al (US Patent 5,494,807, Feb 1996).

Wolfel et al teach as above. However, said reference does not teach the method recited in claim 68 comprising a vector that is a virus as recited in claim 71, that is capable of producing infectious particles in eucaryotic and mammalian cells as recited in claims 72 and 74, wherein said virus naturally has a linear double-stranded DNA as recited in claim 73 and 75, or where the vector is a pox vector such as vaccinia virus vector as recited in claims 76-77, and wherein said method comprises host cells permissive for the production of said virus particles as recited in claim 78, and contains the transcription, translation and termination sequences encompassed by claims 79-91. Paoletti et al teach a vaccinia vector that expresses heterologous epitopes (see column 1) and that has several open reading frames which include the thymidine kinase gene, an inclusion body and a host range gene (column 6) with the transcription, translation and termination sequences encompassed by the instant claims (see entire patent, especially columns 7-8)

Paoletti et al teach that the vaccinia vector can be used for expressing a gene product in a cell cultured in vitro by introducing into the cell a modified recombinant

virus having attenuated virulence and enhanced safety. Paoletti further teaches vaccinia DNA vector with the limitations recited in the instant claims (see entire patent, especially the columns 7-9).

Woeffel teaches a method encompassing a cDNA library wherein the library is a library of heterologous cDNA nucleic acid molecules isolated from a tumor cell (examples 2 and 9) as recited in claims 92-93.

Therefore it would have been obvious to one of skill in the art to have substituted the vaccinia expression vector taught by Paoletti et al for the vectors taught by Woeffel et al in a method for identifying target epitopes taught by Woeffel et al because Paoletti et al teaches it can be used for gene expression with increased safety, and one would have an expectation for success.

Allowable Subject Matter

Claim 116 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers

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for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, PhD
Patent Examiner, Group 1600
June 3, 2002

Amy DeCloux
6-3-02